K090886
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Tunstall

510(k) Summary **Tunstall Healthcare**

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirement of 21 CFR 807.92

APR 15 2009

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Date of summary: February 6, 2009

Common Name: Physiological Transmitter and Receiver
Trade name: RTX3371

Classification name: 21 CFR 870.2910 Physiological Signal Transmitter and Receiver.
Product code: DRG

Predicate Devices:
The RTX3371 device is substantially equivalent to the following predicate devices:

510(k) number:	K071953
Device name:	RTX3370
Applicant:	Tunstall Healthcare

510(k) number:	K072698
Device name:	Confidant 2.5
Applicant:	Confidant International, LLC

Submission Device Description:
The RTX3371 device performs transmission of physiological patient information to and from wireless, infrared and cabled patient monitors, and a remote data server healthcare facility using standard digital communication technologies and protocols.
The RTX3371, with its build-in GSM/GPRS module, transmits data using public wireless networks.
The RTX3371 screen, displays the information or questions about vital signs, symptoms and behaviors sent by the patient's healthcare provider, and allows the patient to respond via four large buttons
The RTX3371 device is not used directly on a patient, and poses no significant risk to the patient or other people within the patient's home.

Intended use and indications for use:
The RTX3371 is for use in non-clinical settings (such as the home), as an accessory device that is intended to be a communication tool to enable health care providers to receive historical patient information. It is intended to be used in combination with a variety of external devices. The RTX3371 serves as the remote communication link between compatible external devices, and the compatible healthcare facility at another location. The healthcare facility could be at a disease management centre or with the healthcare/wellness provider or other out of hospital caregivers. The purpose is to collect and transmit selected medical information (such as weight, blood pressure, blood glucose) using standard wireless technologies.
The RTX3371 does not measure, interpret or make any decisions on the vital data that it conveys.

Substantial Equivalence Comparison table:

Item		Submission device	Predicate device K071953 (Own product)	Predicate device K072698
1	Intended use / Indication for use	See section 2.	See section 9.1. Same, except way of communication with server	See section 9.2.
2	Intended users	Home users and healthcare providers.	Same	Same
3	Site of use	Typically for use in patient's home	Same	Same
4	System description	Telemedicine device that is working as hub/gateway sending measured data from compatible patient monitors to a compatible data server.	Same	Same
5	Appearance	Special designed unit with relatively small display and push buttons for interaction.	Same	Standard Mobile Phone platform with a relatively small display and push buttons for interaction.
6	Connection to patient monitors	Wireless and cable connection between the patient monitors and the device.	Same	Only Wireless connection between the patient monitors and the device.
7	Transmission from device to the server	Standard wireless technologies	Residential telephone line	Standard wireless technologies
8	Patient Interactions	Colour display and push buttons for collection of patient typed data.	Same	Same, but different size of display and buttons.
9	Measurements taken	Blood pressure, weight, ECG, Blood glucose and other measurements provided from compatible monitor devices.	Same	Same

10a	Contra indications and warnings	The device is not for emergency calls, and may not be used to send any real-time alarms or time-critical data.	Same	The device is not intended for emergency calls or for transmission or indication of any real-time alarms or time-critical data.
10b	Contra indications and warnings	All patient medical diagnosis and treatment are to be performed under the supervision and oversight of an appropriate healthcare professional.	Same	All patient medical diagnoses and treatment are to be performed under the supervision and oversight of an appropriate healthcare professional.
10c	Contra indications and warnings	The device is not for use in systems which substitute for medical care.	Same	The device is not intended to provide automated treatment decisions, or to be used as a substitute for professional healthcare judgment
10d	Contra indications and warnings	The device is not for use in systems set up for patients who need direct medical supervision or who might need emergency intervention.	Same	The device is not intended as a substitute for direct medical supervision or emergency intervention.

Discussion of similarities and differences:

Item 1: The submission device and the predicate device K071953 have exactly the same intended use except the way of communication with the server. The products are identical seen from the user, with same functionalities and visual design except the color of the front cover. The way of communication is "Normal residential telephone line" for the predicate device K071953 but "standard wireless technologies" for the submission device and the predicate device K072698. The way of communication is discussed under Item 7.
The overall intended use for the submission device and both predicate devices are the same. The minor differences are discussed in the items below.

Item 2: The submission device and the two predicate devices are all intended to be used by the same group of patients and health care providers.

Item 3: The submission device and the two predicate devices are all intended to be used by patients in their homes.

Item 4: The submission device and the two predicate devices are all collecting data from standard home monitoring devices and transmit the measurements to a database server.

Item 5: The submission device and the predicate device K071953 have identical appearance. The predicate device K072698 is a standard Mobile Phone platform, but seen from the user an almost identical appearance using a small display and a few buttons.

Item 6: The submission device and the predicate device K071953 use exactly the same way of communication technologies with the patient monitors. The predicate device K072698 does not support cable connections to patient monitors, but this does not change the intended use. It only limits the number of supported patient monitors.

Item 7: The predicate device K071953 use a standard residential telephone line as communication between the device and the database server, but both the submission device and the predicate device K072698 use standard wireless technologies. The submission device is based on GSM/GPRS wireless technology like the predicate device K072698.

Item 8: The submission device and the two predicate devices are all based on patient interactions using a relatively small color display and a few push buttons. The submission device and the predicate device K071953 are identical seen from user, and designed to be more user friendly than the predicate device K072698.

Item 9: The submission device and the two predicate devices are all interfacing the same type of home monitoring devices to collect measurements like blood pressure, blood glucose, weight etc.

Item 10: The contra indications and warnings are the same for the submission device and the predicate devices.

Performance data:
The RTX3371 device has been tested to meet the requirements of the following standards and regulations used as acceptance criteria:
IEC 60601-1, IEC 60601-1-2, EN980 and FCC part 15+24.
Risk management is performed according to ISO14971:2000 using FMEA.
Based on the fact that the performance comparison of the predicate devices and the submission device show that the differences are minor and causes no harm to the user, and the fact that the intended use and indication are similar, it was early in the project decided to focus on verification and internal validation instead of large scale validation in form of clinical investigation.
Verification and validation testing activities are successfully conducted according to the company's design control processes to establish performance and reliability characteristics of the device.

Conclusion
The RTX3371 is substantially equivalent to the predicate devices cleared by FDA.
Verification and validation activities demonstrate that safety and effectiveness are acceptable and comparable to the performance of the predicate devices, justifying 510(k) clearance of the device RTX3371.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 15 2009

Tunstall Healthcare
c/o Mr. Niel Ole Anderson
Director of Operations
Stroemmen 6
DK-9400 Noerresundby
Denmark

Re: K090886
Trade/Device Name: RTX3371
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiological signal Transmitter and Receiver
Regulatory Class: Class II (two)
Product Code: DRG
Dated: March 25, 2009
Received: March 31, 2009

Dear Mr. Anderson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K090886

2. Indications for use statement

Indication for Use Statement

510(k) Number (if known):

Device name: RTX3371

The RTX3371 is for use in non-clinical settings (such as the home), as an accessory device that is intended to be a communication tool to enable health care providers to receive historical patient information. It is intended to be used in combination with a variety of external devices. The RTX3371 serves as the remote communication link between compatible external devices, and the compatible healthcare facility at another location. The healthcare facility could be at a disease management centre or with the healthcare/wellness provider or other out of hospital caregivers. The purpose is to collect and transmit selected medical information (such as weight, blood pressure, blood glucose) using standard wireless technologies.
The RTX3371 does not measure, interpret or make any decisions on the vital data that it conveys.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for B Zuckerman

(Division Sign-Off) 4/14/09
Division of Cardiovascular Devices
510(k) Number K090886

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